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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,669	09/17/2003	Satoshi Omura	8012-1018-1	2478

466 7590 09/14/2004

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EXAMINER	
PESELEV, ELLI	
ART UNIT	PAPER NUMBER

1623

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,669	Applicant(s) OMURA ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

The disclosure is objected to because of the following informalities: the status of the patent application no. 10/088,965 has not been updated on page 1 of the specification.

Appropriate correction is required.

Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "method for the differentiation-induction of a monocyte to a macrophage in a patient" (claim 23) has not been described in the specification, as originally filed. Note that page 6 of the specification describes differentiation-induction assay but does not teach said method in a patient.

Claims 1, 8-10 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to describe what is meant by the term "substituents" (claims 1 and 23). The term "substituents" encompasses any chemical moiety such as acyl groups, heterocycles, amino acids, peptides, saccharides, alkyl groups having any number of carbon atoms, etc. The specification fails to provide any teaching or guidance on how to choose specific substituents which will result in compounds having

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the desired activity. Note, that due to the high unpredictability of the activities of compounds having different structural formula, there is a good reason to doubt that, for example, a compound substituted by a methyl group will have the same activity as a compound substituted by a peptide. Since the term "substituents" encompasses such a large number of potential chemical moieties, it would take an undue amount of experimentation to determine which specific substituents will result in compounds having the desired activity.

Claims 1 and 8-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "wherein R1 is Me or I-Pr, R2 is not H" renders claim 1 indefinite. Such terminology as "wherein when R1 is Me or I-Pr, R2 is not H" can be used to overcome the rejection.

The term "substituents" (claims 1 and 23) renders the claims indefinite since it is not clear what is encompassed by said term i.e. the scope of the invention cannot be determined. Note that the specification fails to provide definition for the term "substituents".

Claims 1 and 8-10 are substantial duplicates.

Claims 11-14 are substantial duplicates.

Claims 15-18 are substantial duplicates.

Claims 19-22 are substantial duplicates.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,734,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compounds are encompassed by the patented compounds.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 22 of prior U.S. Patent No. 6,734,292. This is a double patenting rejection.

Claim 15 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 24 of prior U.S. Patent No. 6,734,292. This is a double patenting rejection.

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Claim 19 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 28 of prior U.S. Patent No. 6,734,292. This is a double patenting rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoeltje et al (U.S. Patent No. 5,418,224), Kirst et al (U.S. Patent No. 5,106,961) or Gidda et al (U.S. Patent No. 4,920,102).

Hoeltje et al disclose the claimed compounds wherein one of R1 or R2 is Me or H and the other is isopropyl and administering said compounds to patients.

Each of Kirst et al or Gidda et al discloses the claimed compounds wherein each of R1 and R2 is methyl and administering said compounds to patients.

The claimed compounds and methods are anticipated by Hoeltje et al, Kirst et al or Gidda et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

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